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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,163	01/18/2001	Brian J. Nickoloff	ISPH-0531	6074

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EXAMINER

ROARK, JESSICA H

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/743,163	Applicant(s) NICKOLOFF, BRIAN J.	
	Examiner Jessica H. Roark	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jessica Roark, Art Unit 1644, Technology 1600.
2. Applicant's amendment, filed 8/21/03, is acknowledged.
 - Claims 2-22 have been canceled.
 - Claim 1 has been amended.
 - Claim 1 is pending and under consideration in the instant application.
3. It is noted that New Grounds of Rejection are set forth herein. This Office Action is therefore Non-Final.

IDS

4. Applicant's comments in response to the Examiner's comments of record are acknowledged. The current Examiner notes that an IDS was previously filed by Applicant and considered by the Examiner. The Examiner's comments of record were drawn to the listing of references that appears on pages 46-50 of the specification. References which are not listed on a PTO-1449 are not considered by the Examiner and will not print on the face of a patent that issues from a specification containing such embedded references.

Specification

5. This application does not appear to contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

Priority

7. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, provisional application 60/092,151 to which priority is claimed does not appear to provide adequate support under 35 U.S.C. 112 for instant claim 1 because the Examiner was unable to locate any mention of a method of inhibiting a NK-T cell-mediated reaction by administering an antibody to CD1d.

Should the Applicant disagree with the Examiner's factual determination above, it is incumbent upon the Applicant to provide a showing that specifically supports the instant claim limitations.

Therefore, the instant claims do not appear to be entitled to the 7/9/1998 filing date of provisional application 60/092,151.

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35 USC § 112 first paragraph

8. Applicant's amendment, filed 8/21/03, has obviated the previous rejections of record under 35 USC 112, first paragraph by limiting the scope of the instant claim.

Claim Rejections – 35 U.S.C. §§ 102 and 103

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Panja et al. (J. Exp. Med. 1993; 178:1115-1119, see entire document).

Panja et al. teach that an antibody to CD1d can inhibit T cell proliferation in cultures of normal human epithelial cells and human T cells (see entire document, but especially page 1116, 2nd column, 1st paragraph).

Because Panja et al. teach that contacting human T cells and epithelial cells with an anti-CD1d antibody inhibits proliferation, cells in the culture must have expressed CD1d (which is an MHC class I-like molecule) and the T cells whose proliferation was inhibited must necessarily have been NK-T cells which express CD161.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations, including inhibiting the interaction of an MHC class I-like molecule with the NK-T cell receptor CD161, would be inherent in the method of Panja et al. which contacts cells with an anti-CD1d antibody.

The reference teachings thus anticipate the instant claimed invention.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Exley et al. (J. Exp. Med. 1997; 186:109-120, see entire document).

Exley et al. teach contacting human NK T cell clones with an antibody to CD1d and that the addition of anti-CD1d antibody to cell line cultures could block activation of the NK T cell clones normally produced by co-culture with CHO cells transfected with CD1d (see entire document, but especially page 114, 1st full paragraph). Although Exley et al. do not call these cells "NK-T" cells, they do show that the cells have characteristics of both T cells and NK cells, including expression of NKR-P1 and T cell receptor, and that this cell population is the human equivalent of murine NK1⁺ T cells (see e.g., page 110, 1st full paragraph).

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Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations, including inhibiting the interaction of an MHC class –like molecule with the NK-T cell receptor CD161, would be inherent in the method of Exley et al. which contacts cells with an anti-CD1d antibody.

The reference teachings thus anticipate the instant claimed invention.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Porcelli et al. (U.S. Pat. No. 5,679,347, see entire document).

Porcelli et al. teach blocking agents to CD1, including CD1d, and that antibodies can be blocking agents (see entire document, but especially column 16 at lines 47-54, column 20 at lines 5-41 and Example 11 at columns 35-37). Porcelli et al. teach that CD1 blocking agents, including antibodies, are useful for controlling undesired immunity, including the in vivo immune reactions that occur in autoimmunity (e.g., column 35 at lines 10-25).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations, including inhibiting the interaction of an MHC class –like molecule with the NK-T cell receptor CD161, would be inherent in the method taught by Porcelli et al. to block CD1, including CD1d, interactions in vivo by administering an antibody to CD1.

The reference teachings thus anticipate the instant claimed invention.

13. As noted supra, the instant claim is not considered to have benefit of the filing date of provisional application 60/092,151. The following rejection under 35 U.S.C 102(e) is therefore also set forth.

14. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Porcelli et al. (U.S. Pat. No. 5,679,347, see entire document).

Porcelli et al. teach blocking agents to CD1, including CD1d, and that antibodies can be blocking agents (see entire document, but especially column 16 at lines 47-54, column 20 at lines 5-41 and Example 11 at columns 35-37). Porcelli et al. teach that CD1 blocking agents, including antibodies, are useful for controlling undesired immunity, including the in vivo immune reactions that occur in autoimmunity (e.g., column 35 at lines 10-25).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations, including inhibiting the interaction of an MHC class –like molecule with the NK-T cell receptor CD161, would be inherent in the method taught by Porcelli et al. to block CD1, including CD1d, interactions in vivo by administering an antibody to CD1.

The reference teachings thus anticipate the instant claimed invention.

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Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number for before Final submissions is (703) 872-9306.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
October 29, 2003

PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER
TCH CENTER 1600
01/30/03